

**Pharmaceutical Waste Handling: Violations Seen
by County Inspectors**

*Presented by John Misleh, County of San Diego, Dept. of
Environmental Health, Hazardous Materials Division
May 11, 2011*



1

**Some common pharmaceutical waste
violations observed during the past 2
years of County inspections**

- Waste container labeling was not correct
- Failed to segregate waste properly
- Failed to properly classify the waste type
- Could not find the records/tracking documents of waste disposal
- Improper disposal to trash, garbage, & local landfill
- Improper storage of the waste
- Poor recordkeeping

And some others.....²

**1(a). Pharmaceutical medical waste,
improper/missing container labeling is a
common violation**

Correct: Place the waste in a container or secondary container; that container shall be labeled with the words **"INCINERATION ONLY"** on the lid and on the sides, so as to be visible from any lateral direction, to ensure treatment of the waste.

3

**1(b). Container labeling issue
continued**

RCRA hazardous waste pharmaceutical
container not properly labeled.

Correct: Hazardous waste pharmaceuticals must be labeled with a hazardous waste label that says: the name and address of waste generator, waste composition, physical state, the words "hazardous waste", warning or hazardous properties, and the initial waste accumulation start date.

4

**1(c) Pharmaceutical medical waste
container not labeled properly per
local ordinance**

Correct: In San Diego County because of a local county ordinance, the container labeling must also have this information about the waste generator:

- Generator's name
- Generator's address
- Generator's phone number

5



Pain relief clinic in the County of San Diego, 2009. Waste was not labeled, placed in a black trash bag by facility. Facility unsure about all the different medications that were in the container.

6



Close up of the pharmaceutical waste seen in previous slide.

7



Hazardous waste container not labeled properly. Missing business name, address, contents, physical state, hazard properties, and accumulation start date. Corrected during the inspection.

8



Hazardous waste container not labeled properly. contents, physical state, hazard properties, and accumulation start date. Corrected during the inspection.

9



Pharmacy area- Hazardous waste container not properly labeled. Missing business name, address, hazard properties, physical state, the words "hazardous waste" and waste accumulation start date.

10



Other side of the improperly labeled container shown in prior photo. The hazardous waste container is labeled with conflicting information.

11



Hazardous waste not closed or labeled properly with the composition , generator's name and address, hazardous properties, and the waste accumulation start date.

12



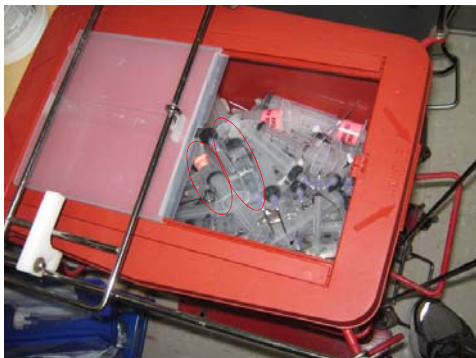
RCRA hazardous waste container observed missing the waste accumulation start date , the words "hazardous waste", and the waste generators name and address.

13



Pharmaceutical waste container labeled as both RCRA hazardous waste and pharmaceutical waste. The RCRA hazwaste label was incorrect and defaced during the inspection.

14



Pharmaceutical sharp waste not properly labeled as pharmaceutical waste "incinerate only". This waste does not contain an infectious agent or have any contact with a patient per the Clinical Pharmacist on duty.

15

2(a) Storage of pharmaceutical medical waste for too long onsite

Correct: for waste that meets the definition of non-RCRA pharmaceutical medical waste, a person may store their medical waste at an onsite location for not longer than 90 days when the container is ready for disposal. The waste shall be disposed of at least once per year.

Non-RCRA means California regulated and not subject to the Federal RCRA hazardous waste law.

16

2(b) Storage of RCRA hazardous waste pharmaceuticals for too long

Correct: Hazardous waste onsite accumulation shall be for:

- < 90 days onsite if a large quantity generator.
- < 180 days onsite if a small quantity generator.
- < 270 days onsite if a small quantity generator and the waste is shipped offsite more than 200 miles.

17

3. Comingling different medical wastes in common container

Correct: A person may consolidate into a common container all medical waste provided that the consolidated waste is treated by a high heat technology that is State approved. The container shall be labeled with the biohazardous waste symbol and the words "HIGH HEAT ONLY" on the lid and on the sides, to ensure treatment of the biohazardous.

18



Sharps container observed with pharmaceutical vials mixed with sharps waste.

19

4. Failure to make a proper waste classification at the point of origin

Problem: The pharmaceutical waste is disposed of improperly or stored incorrectly because the waste generator did not classify it correctly at the point of origin.

Correct: To containerize or store medical waste, a person shall do the following: medical waste shall be contained separately from other waste at the point of origin in the producing facility.

20

5. Lack of pharmaceutical medical waste disposal records/tracking documents available for review during the inspection

Correct:

- A large quantity medical waste generator (≥ 200 pounds in any month) shall keep waste tracking records (disposal records) for 3 years.
- A small quantity generator who treats any of their medical waste onsite shall keep records for 3 years.
- A small quantity generator who uses a waste transportation and offsite disposal service must keep at least 2 years of records.

21

6. Placing open, dispensed pharmaceutical medical waste in with the reverse distributor's credit shipment

Correct: EPA has provided guidance; they said there must be a reasonable expectation of proper use ..e.g..the underlying assumption is that the returned product will be recycled or used.

Weblink to EPA's guidance letter:

[http://yosemite.epa.gov/osw/rcra.nsl/0C994248c239947e85256d090071175f/A3A7A7A8F29743888525670F0068E5D8/\\$file/11606.pdf](http://yosemite.epa.gov/osw/rcra.nsl/0C994248c239947e85256d090071175f/A3A7A7A8F29743888525670F0068E5D8/$file/11606.pdf)

- It remains the generator's responsibility to properly identify their waste material at the source.
- Do not add waste in with the reverse distributor shipment.

22

7. Pharmaceutical waste mixed in with other biohazardous wastes

Correct: if different wastes are mixed, it is subject to the State's high heat incineration requirement, special labeling, and storage time limit of the waste type with the most stringent time limit standard.

- Mixing is not recommended. Possibly more expensive to dispose of. Limited offsite facilities that will accept the waste.

23

8. Illegal disposal of pharmaceutical waste by generator

Correct:

The waste generator must not mix pharmaceutical waste with regular trash, hospital garbage, or pour down the drain.

- Pharmaceutical waste must be identified, segregated at the point of origin, and placed in the proper waste accumulation containers.

24



Pharmaceutical waste found in clear trash bag at local landfill. (next slide is a close up photo)

25



Close up of pharmaceutical waste DIPRIVAN 1% PROPOFOL in trash at local landfill.

26

Anesthetic solution waste found at local landfill



Discarded pharmaceutical medical waste bottle found in waste with a small amount of clear liquid seen in this closed bottle at a local landfill.

27



1/2 full container of pharmaceutical medical waste, antifungal powder at local landfill .

28



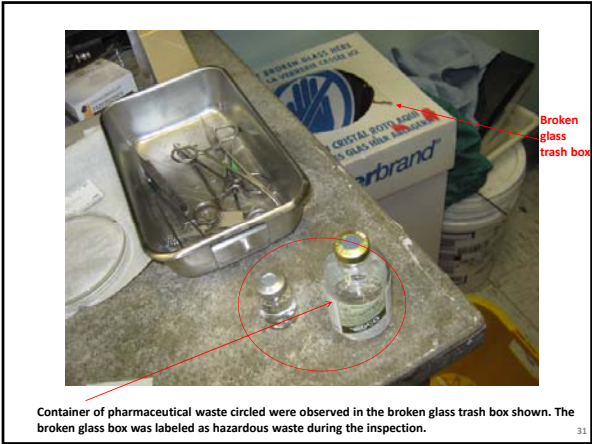
Full container of iodine containing waste at local landfill. Waste came from a Surgery Room.

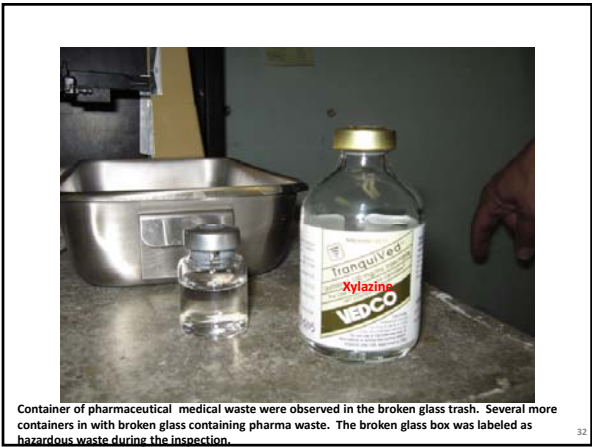
29

9. Mixing pharmaceutical waste in with the contaminated/broken glass storage box

Correct: Make sure pharmaceutical waste is not placed into contaminated or broken glass container. The pharmaceutical container can go into the contaminated glass container if it is empty and not a acute hazardous waste (P listed) under RCRA (unless tripled rinsed).

30







Other miscellaneous things Inspectors have seen, next few photos



Pharmaceutical waste was stored in 5-gallon buckets which are labeled Non-controlled drugs. But some DEA regulated controlled substances were observed inside the bucket, such as Morphine. (next few slides show the contents better)

34



View of various pharmaceutical waste stored inside a 5-gallon container.

35



An ampoule of unused Epinephrine was observed inside the 5-gallon container .

36



An unused syringe of Morphine Sulfate solution was observed inside the 5-gallon container that was used to store Non-Controlled substances.

37

10. Trace Chemo waste not properly labeled

Correct:

Waste contaminated through contact with, or having previously contained, chemo-therapeutic agents, shall be segregated for storage, that container shall be labeled with the words "Chemotherapy Waste", "CHEMO", on the lid and on the sides, so as to be visible from any lateral direction, to ensure treatment of the biohazardous waste.

Sharps waste, shall be placed in sharps containers labeled in accordance with the industry standard with the words "Chemo-therapy Waste", "Chemo", and segregated to ensure treatment of the sharps waste.

38



Trace chemo waste bag was observed being stored on the floor. This violation was corrected during the inspection.

39



RCRA pharmaceutical hazardous waste containers were not properly labeled with the accumulation start date and the contents/composition. Red bag not tied off or containerized in a rigid container. Containers not stored to prevent a spill.

40



Non-empty pharmaceutical waste vials were removed from a dumpster. The bottles were placed in a pharmaceutical waste container during the inspection.

41

11. Waste Generator's Medical Waste Management Plan on file missing information about pharmaceutical medical waste

- County has a medical waste management plan form that asks for the estimated amount of pharmaceutical medical waste generated per month. Form is at:

<http://www.sdcounty.ca.gov/deh/hazmat/pdf/hm-9213.pdf>

California regulated pharmaceutical waste, estimated monthly amount?

42

Some resources: EPA's RCRA hazwaste
and California's regulation

- <http://water.epa.gov/scitech/wastetech/guide/upload/unuseddraft.pdf> *August 2010 Guidance Document: Best Management Practices for Unused Pharmaceuticals at Health Care Facilities (Draft)*
- <http://sfwater.org/Files/FactSheets/CaliforniaBlueprintFinalDraft80908.pdf> *A 10-Step Blueprint for Healthcare Facilities In the United States, Revised for California Healthcare Facilities, August 2008*

43

**County of San Diego's Medical Waste
Information/Regulations/Publications
Webpage**

- Webpage at:
http://www.sdcounty.ca.gov/deh/hazmat/med_waste.html

44
